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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0029]

Indevus Pharmaceuticals, Inc.; Withdrawal of Approval of a New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for REDUX (dexfenfluramine hydrochloride (HCl)) Capsules held by Indevus Pharmaceuticals, Inc. (Indevus), 33 Hayden Ave., Lexington, MA 02421-7971. Indevus has requested that approval of this application be withdrawn because the product is no longer marketed, thereby waiving its opportunity for a hearing.

DATES: Effective [insert date of publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

Florine P. Purdie,

Center for Drug Evaluation and Research (HFD-7),

Food and Drug Administration,

5600 Fishers Lane,

Rockville, MD 20857,

301-594-2041.

SUPPLEMENTARY INFORMATION: In 1997, FDA asked that REDUX (dexfenfluramine HCl) be withdrawn from the market because of safety concerns; Indevus (formerly Interneuron Pharmaceuticals, Inc.) discontinued marketing this product. REDUX (dexfenfluramine HCl)

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Capsules, a treatment for obesity, was withdrawn from the market after review of safety data showed that the product is associated with valvular heart disease (see FDA press releases on "Health Advisory on Fenfluramine/Phentermine for Obesity," dated July 8, 1997, (http://www.fda.gov/opacom/hpnews.html), and "FDA Announces Withdrawal of Fenfluramine and Dexfenfluramine," dated September 15, 1997, (http://www.fda.gov/opacom/hpnews.html)).

In a letter dated January 16, 2006, Indevus requested that FDA withdraw approval, under § 314.150(d) (21 CFR 314.150(d)), of NDA 20-344 for REDUX (dexfenfluramine HCl) Capsules, stating that it had discontinued marketing the product. The letter also stated that Indevus believes that the risk/benefit ratio for the use of dexfenfluramine is unfavorable and that withdrawal of approval of NDA 20-344 is in the best interest of public health. Indevus voluntarily waived its opportunity for a hearing, provided under § 314.150(a) and (b).

Therefore, under section 505(e) of Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)), § 314.150(d), and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs, approval of NDA 20-544, and all amendments and supplements thereto, is withdrawn, effective [insert date of publication in the FEDERAL

REGISTER]. Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the act (21 U.S.C. ~~355(a) and~~ 331(d)).

1-19-07
SR
Section 505 already defined

Dated: 1/12/07
January 12, 2007.

Douglas C. Throckmorton,
Deputy Director,
Center for Drug Evaluation and Research.

SR
per CFR style

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]
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Dawn P. Hawkins